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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/727,480	12/04/2000	Sara Alajem	00/21400	4363

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT PAPER NUMBER

1637

DATE MAILED: 07/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/727,480

Applicant(s)

Alajem et al

Examiner

Jeffrey Fredman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 17, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 87-92 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 87-92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 87-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is vague and indefinite what is meant by the phrase "first region being capable of hybridising" in claim 87, as well as "Capable of forming a duplex". The phrase "capable of" renders the claims indefinite because the capacity of a probe to perform some function is merely a latent characteristic of the probe and this language carries no patentable weight. See MPEP § 2173.05(b).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 87 are rejected under 35 U.S.C. 102(b) as being anticipated by Hogan et al (U.S. Patent 5,451,503).

Hogan teaches a method for detecting the presence or the absence of a target nucleic acid sequence in a sample (column 6 and column 35, claim 1) comprising the steps:

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a) contacting the sample with an oligonucleotide system under hybridization conditions so as to form a reaction mixture (see figure 15 E) where said oligonucleotide system includes two oligonucleotides, one "anchor oligonucleotide" which has two regions, one which hybridizes to the target and one which hybridizes to an "amplifier oligonucleotide" (see figure 15 E) and where the "amplifier oligonucleotide" also has two regions, one which hybridizes to the target and one which hybridizes to the "anchor oligonucleotide" (see figure 15 E), which includes a sequence which, upon formation of a duplex, will be recognized by the nuclease cleavage reagent RNase H (figure 15 E) and where the RNase H cleavage reagent will cleave only the "amplifier oligonucleotide" but not the "anchor oligonucleotide" (see figure 15 E) and where cleavage of the "amplifier oligonucleotide" leads to the dissociation of the "anchor oligonucleotide" (see column 21, lines 45-57 and column 22, lines 10-16), thus enabling recycling of the anchor oligonucleotide target sequence hybrid with respect to the amplifier oligonucleotide (see column 22, lines 10-16)

b) adding a cleaving agent, where the nuclease may include RNase H, which cleaves only the RNA strand and not the DNA strand, thus cleaving only a single strand (column 4, lines 21-54) and permitting recycling (see column 22, lines 10-16),

c) monitoring the presence or absence of cleavage products (column 36, claim 6, column 37, claim 7 or column 6, line 31 to column 7, line 24).

Hogan expressly teaches the instance where cleavage of the arm regions reduces the stability of the complex, thereby resulting in dissociation of the probe regions from the target (column 21, lines 33-42).

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Hogan expressly teaches the use of modified nucleotides in the probes such as phosphorothioates which prevent cleavage by the cleaving agent (column 6, lines 11-26).

Hogan further expressly teaches that this dissociation can enable a second assembly to hybridize with the target sequence (column 21, lines 39-42).

Hogan teaches the use of probes where the T_m of the regions differ by 10 C (see column 2, lines 60-64).

Response to Arguments

4. Applicant's arguments filed June 17, 2002 have been fully considered but they are not persuasive. .

Applicant argues that the Hogan reference does not anticipate the new claims for several reasons. First applicant states "Applicant wishes to point out that, in contrast to the nucleic acid cleavage site described by Hogan et al., the cleavage site formed by hybridization of the anchor and amplifier oligonucleotides utilized by the method of the present invention, while double stranded in it's recognition sequence, is cleaved only on one strand sicne the complementary strand is nicked (page 9 of response)". This argument is not correct. As figure 15 E clearly shows, Hogan teaches an embodiment in which only one strand is cleaved.

Applicant then argues that a comparison with Hogan was performed. No comparison with the method shown by Hogan in figure 15 E was found in the specification.

Therefore, Applicant's arguments are not found persuasive and the rejection over Hogan is maintained. The remaining rejections are withdrawn in view of the amendment.

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Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman, Ph.D. whose telephone number is (703) 308-6568.

The examiner is normally in the office between the hours of 6:30 a.m. and 4:00 p.m., and telephone calls either in the morning are most likely to find the examiner in the office.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).



Jeffrey Fredman
Primary Patent Examiner
Art Unit 1655

July 19, 2002